UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: DAVOL, INC./C.R. BARD, INC., POLYPROPYLENE HERNIA MESH PRODUCTS LIABILITY LITIGATION

Case No. 2:18-md-2846

JUDGE EDMUND A. SARGUS, JR.
Magistrate Judge Kimberly A. Jolson

This document relates to:
Milanesi, et al. v. C.R. Bard, Inc., et al.
Case No. 2:18-cv-01320

EVIDENTIARY MOTIONS OPINION AND ORDER No. 18

Before the Court is Plaintiffs' Motion to Exclude the Opinions and Testimony of Defense Expert Dr. Prashant Sinha, M.D. (ECF No. 82.) For the reasons below, Plaintiffs' motion is **GRANTED IN PART, DENIED IN PART, AND DENIED IN PART AS MOOT**.

I. Background[1]

Plaintiffs', Antonio Milanesi and Alicia Morz de Milanesi, case is the second bellwether trial selected from thousands of cases in this multidistrict litigation ("MDL") against Defendants, C.R. Bard, Inc. and Davol, Inc. The Judicial Panel on Multidistrict Litigation described the cases in this MDL as "shar[ing] common factual questions arising out of allegations that defects in defendants' polypropylene hernia mesh products can lead to complications when implanted in patients, including adhesions, damage to organs, inflammatory and allergic responses, foreign body rejection, migration of the mesh, and infections." (Case No. 2:18-md-02846, ECF No. 1 at PageID #1–2.)[2] This includes Defendants' Ventralex Hernia Patch, the device implanted in

[1] For a more complete factual background, the reader is directed to the Court's summary judgment opinion and order. (ECF No. 167.)

[2] All docket citations are to the docket in the instant case, Case No. 18-cv-1320, unless otherwise noted.

Mr. Milanesi.

The Ventralex is a prescription medical device used for umbilical and small ventral hernia repairs. (ECF No. 167 at PageID #13610.) The small and medium sizes were cleared through the 510(k) premarket notification process by the Food and Drug Administration ("FDA") in 2002; the Composix Kugel was listed as a predicate device. (*Id.* at PageID #13611.) The large size was cleared via "a no 510(k) rationale based upon the 510(k) for the Composix Kugel product." (*Id.*) The Ventralex has two sides—one of polypropylene mesh and one of permanent expanded polytetrafluoroethylene ("ePTFE"). (*Id.* at PageID #13610.) The polypropylene mesh side faces the abdominal wall, encouraging tissue to grow into the mesh and thus supporting the hernia repair. The ePTFE side faces the intestines and is designed to minimize tissue attachment, such as adhesions, to the intestines and other viscera. The Ventralex also has a monofilament memory coil ring, which was made of polyethylene terephthalate ("PET") when it was implanted in Mr. Antonio. The ring is designed to help the patch "pop open" and then "lay flat" against the abdominal wall after the Ventralex is folded and inserted through the incision site during surgical repair of the hernia. (*Id.*)

Plaintiffs bring this action to recover for injuries sustained as a result of the implantation of Defendants' allegedly defective Ventralex device. Ten years after the implantation of the Ventralex, Mr. Milanesi underwent surgery to repair what appeared to be a recurrent hernia but was revealed to be a bowel erosion with a fistula and adhesions, which required a bowel resection. (*Id.* at PageID #13610–13.) Shortly thereafter, Mr. Milanesi suffered a high-grade post-operative small bowel obstruction that required emergency surgery. (*Id.* at PageID #13613.)

The crux of Plaintiffs' claims is that Defendants knew of the risks presented by the Ventralex device but marketed and sold the device despite these risks and without appropriate

warnings. Plaintiffs point to three specific issues with the Ventralex: (1) polypropylene resin oxidatively degrades *in vivo*, (2) the ePTFE layer contracts more quickly than the polypropylene, which in combination with the too-weak memory coil ring causes the device to fold or buckle or "potato chip," leading to the exposure of the bare polypropylene to the bowel, and (3) the ePTFE layer is prone to infection. (*Id.* at PageID #13613–14.) After summary judgment, the following claims remain for trial: defective design (strict liability), failure to warn (strict liability), negligence, gross negligence, negligent misrepresentation, fraud and fraudulent misrepresentation, fraudulent concealment, loss of consortium, and punitive damages. (*Id.* at PageID #13616–37.)

The parties have filed their dispositive and *Daubert* motions, and the motions are now ripe for adjudication, including the present motion.

II. Legal Standard

"Neither the Federal Rules of Evidence nor the Federal Rules of Civil Procedure explicitly authorize a court to rule on an evidentiary motion *in limine*." *In re E.I. du Pont de Nemours & Co. C-8 Pers. Injury Litig.*, 348 F. Supp. 3d 698, 721 (S.D. Ohio 2016). The practice of ruling on such motions "has developed pursuant to the district court's inherent authority to manage the course of trials." *Luce v. United States*, 469 U.S. 38, 41 n.4 (1984). "The purpose of a motion *in limine* is to allow a court to rule on issues pertaining to evidence prior to trial to avoid delay and ensure an evenhanded and expedient trial." *In re E.I. du Pont*, 348 F. Supp. 3d at 721 (citing *Ind. Ins. Co. v. Gen. Elec. Co.*, 326 F. Supp. 2d 844, 846 (N.D. Ohio 2004)). However, courts are generally reluctant to grant broad exclusions of evidence before trial because courts are "almost always better situated during the actual trial to assess the value and utility of evidence." *Jackson v. Cnty. of San Bernardino*, 194 F. Supp. 3d 1004, 1008 (C.D. Cal. July 5, 2016) (quoting *Wilkins v. Kmart Corp.*, 487 F. Supp. 2d 1216, 1218 (D. Kan. 2007)); *accord Sperberg v. Goodyear Tire & Rubber Co.*,

519 F.2d 708, 712 (6th Cir. 1975) ("A better practice is to deal with questions of admissibility of evidence as they arise."). Unless a party proves that the evidence is clearly inadmissible on all potential grounds—a demanding requirement—"evidentiary rulings should be deferred until trial so that questions of foundation, relevancy and potential prejudice may be resolved in proper context." *In re E.I. du Pont*, 348 F. Supp. 3d at 721 (quoting *Ind. Ins. Co*., 326 F. Supp. 2d at 846). The denial, in whole or in part, of a motion in limine does not give a party license to admit all evidence contemplated by the motion; it simply means that the Court cannot adjudicate the motion outside of the trial context. *Ind. Ins. Co.*, 326 F. Supp. 2d at 846.

The burden is on the party offering the expert opinions and testimony to demonstrate "by a preponderance of proof" that the expert evidence is admissible. *Nelson v. Tenn. Gas Pipeline Co.*, 243 F.3d 244, 251 (6th Cir. 2001). Any doubts regarding the admissibility of an expert's testimony should be resolved in favor of admissibility. *See Jahn v. Equine Servs., PSC*, 233 F.3d 382, 388 (6th Cir. 2000) ("The Court [in *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993),] explained that Rule 702 displays a 'liberal thrust' with the 'general approach of relaxing the traditional barriers to "opinion" testimony.'" (quoting *Daubert*, 509 U.S. at 588)); Fed. R. Evid. 702 advisory committee's note to 2000 amendment ("A review of the case law after *Daubert* shows that the rejection of expert testimony is the exception rather than the rule.").

III. Analysis

The district court's role in assessing expert testimony is a "gatekeeping" one, "screening expert testimony" so that only admissible expert testimony is submitted to the jury; its role is not to weigh the expert testimony or determine its truth. *United States v. Gissantaner*, 990 F.3d 457, 463 (6th Cir. 2021) (quoting *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 597 (1993)). Expert testimony, testimony given by "[a] witness who is

qualified as an expert by knowledge, skill, experience, training, or education," is admissible if:

> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
> (b) the testimony is based on sufficient facts or data;
> (c) the testimony is the product of reliable principles and methods; and
> (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702. In this circuit, "[t]he Rule 702 analysis proceeds in three stages." *United States v. Rios*, 830 F.3d 403, 413 (6th Cir. 2016). "First, the witness must be qualified by 'knowledge, skill, experience, training, or education.' Second, the testimony must be relevant, meaning that it 'will assist the trier of fact to understand the evidence or to determine a fact in issue.' Third, the testimony must be reliable." *In re Scrap Metal Antitrust Litig.*, 527 F.3d 517, 529 (6th Cir. 2008) (quoting Fed. R. Evid. 702.).

First, an expert witness must be qualified by "knowledge, skill, experience, training, or education." Fed. R. Evid. 702. "[T]he issue with regard to expert testimony is not the qualifications of a witness in the abstract, but whether those qualifications provide a foundation for a witness to answer a specific question." *Madej v. Maiden*, 951 F.3d 364, 370 (6th Cir. 2020) (quoting *Berry v. City of Detroit*, 25 F.3d 1342, 1351 (6th Cir. 1994)). "[T]he only thing a court should be concerned with in determining the qualifications of an expert is whether the expert's knowledge of the subject matter is such that his opinion will likely assist the trier of fact in arriving at the truth. The weight of the expert's testimony must be for the trier of fact." *Mannino v. Int'l Mfg. Co.*, 650 F.2d 846, 851 (6th Cir. 1981). A party's expert need only meet the "'minimal qualifications' requirement—not one who could teach a graduate seminar on the subject." *Burgett v. Troy-Bilt LLC*, 579 F. App'x 372, 377 (6th Cir. 2014) (quoting *Mannino*, 650 F.2d at 851); *see*

also Dilts v. United Grp. Servs., LLC, 500 F. App'x 440, 446 (6th Cir. 2012) ("An expert's lack of experience in a particular subject matter does not render him unqualified so long as his general knowledge in the field can assist the trier of fact.").

Second, expert testimony must be relevant. Expert testimony is relevant if it will "help the trier of fact to understand the evidence or to determine a fact in issue." *Bradley v. Ameristep, Inc.*, 800 F.3d 205, 208 (6th Cir. 2015) (quoting *United States v. Freeman*, 730 F.3d 590, 599–600 (6th Cir. 2013)); Fed. R. Evid. 702(a). "Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful." *Daubert*, 509 U.S. at 591 (quoting 3 Jack B. Weinstein & Margaret A. Berger, Weinstein's Evidence ¶ 702[02], p. 702–18 (1988)). "This requirement has been interpreted to mean that scientific testimony must 'fit' the facts of the case, that is, there must be a connection between the scientific research or test result being offered and the disputed factual issues in the case in which the expert will testify." *Pride v. BIC Corp.*, 218 F.3d 566, 578 (6th Cir. 2000) (citing *Daubert*, 509 U.S. at 592). This is a case-specific inquiry. *See Madej*, 951 F.3d at 370 ("Whether an opinion 'relates to an issue in the case' or helps a jury answer a 'specific question' depends on the claims before the court.").

Third, expert testimony must be reliable. Rule 702 provides the following general standards to assess reliability: whether "the testimony is based on sufficient facts or data," whether "the testimony is the product of reliable principles and methods," and whether "the expert has reliably applied the principles and methods to the facts of the case." Fed. R. Evid. 702(b)–(d). To evaluate reliability of principles and methods, courts consider "'testing, peer review, publication, error rates, the existence and maintenance of standards controlling the technique's operation, and general acceptance in the relevant scientific community,'" though these "factors 'are not dispositive in every case' and should be applied only 'where they are reasonable measures of the

reliability of expert testimony.'" *In re Scrap Metal*, 527 F.3d at 529 (citations omitted); *see Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 150 (1999) (describing these factors as "flexible" (quoting *Daubert*, 509 U.S. at 594)). The objective of the reliability requirement is to "make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire*, 526 U.S. at 152.

Plaintiffs challenge the opinions of Dr. Prashant Sinha, M.D. They argue these opinions should be excluded: (A) adverse event data and adverse event and complication rate opinions, (B) polypropylene degradation and biomaterial testing opinions, (C) specific causation and case-specific opinions, (D) opinions on the adequacy of the Ventralex IFU and the meaning of the 510(k) process, (E) legal and ethical opinions, and (F) gold standard and standard of care opinions. Dr. Sinha cannot offer his adverse-event opinions that extend beyond his personal experience, his biomaterial testing opinions, his opinions about the meaning of the 510(k) process, or his legal opinions. Defendants must produce that data Dr. Sinha indicated that he relied on in reaching some of his adverse-event opinions, and Plaintiffs will be permitted to conduct a supplemental deposition of Dr. Sinha regarding his adverse-outcome opinions that relied on previously undisclosed data.

A. Adverse event data and complication rates

Plaintiffs argue that Dr. Sinha's opinions relying on undisclosed data should be excluded for a lack of compliance with Federal Rule of Civil Procedure 26(a)(2)(B) and because these opinions are unreliable under Federal Rule of Evidence 702.[3] (ECF No. 82 at PageID #5342–51.)

[3] Plaintiffs also assert that Dr. Sinha's opinions here do not fit the case, meaning they are irrelevant, (ECF No. 82 at PageID #5345), but Plaintiffs do not develop this

Defendants counter that Dr. Sinha offers opinions on complications, or lack thereof, based on his personal experience as a hernia surgeon, meaning there is no untimely disclosure issue, and that his opinions are reliable. (ECF No. 101 at PageID #8588–89.) Dr. Sinha's opinions about adverse events that are based on his personal experience relied on properly disclosed information and are reliable. However, his adverse-event opinions that rely on data depend on undisclosed data, and his opinions that necessarily extend beyond his personal experience with patients are unreliable.

Adverse-event opinions based on personal experience. To the extent that Dr. Sinha bases his opinions about adverse patient outcomes solely on his personal experience, there is no untimely disclosure issue, and his opinions are reliable. As this Court has concluded before, "it is 'well-established that experience-based testimony satisfies Rule 702 admissibility requirements." *In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Prods. Liab. Litig.*, Nos. 2:18-cv-01509, 2:18-md-2846, 2020 WL 6605612, at *13 (S.D. Ohio Sept. 11, 2020) (quoting *In re E.I. du Pont de Nemours & Co. C-8 Pers. Injury Litig.*, 345 F. Supp. 3d 897, 902 (S.D. Ohio 2015)) (Evidentiary Motions Order ("EMO") No. 7). Moreover, Dr. Sinha provided additional explanations for his experience-based opinions. For example, Dr. Sinha did not simply opine that he has never seen evidence of buckling, erosion, extrusion, etc. in his patients; he also opined that these issues do not happen with proper fixation and placement and that the contraction, shrinkage, buckling he has seen in his patients is due to scar tissue. (ECF No. 82-5 at PageID #5470–71; ECF No. 82-7 at PageID #5576–77.) This is sufficient and gives Plaintiffs an adequate basis on which to test Dr. Sinha's opinions during trial. Relatedly, Plaintiff argues that Dr. Sinha's testimony about outcomes amounts to adverse event rates, rendering his opinions unreliable without explicit data

argument. In any case, Dr. Sinha's adverse data and complication rate opinions fit this case because they address the pertinent complications and devices in this case.

to support his conclusions. (ECF No. 82 at PageID #5349.) Dr. Sinha's statements that he has never seen certain complications under some situations or that complications are rare are not rate-based opinions that would require specific data to be reliable.

Adverse-event opinions based on data. In some instances, Dr. Sinha's deposition testimony blurs the line between his opinions based on personal experience and opinions based on specific data, and this data was not disclosed previously. When discussing his opinion that chronic pain was an infrequent occurrence, Dr. Sinha explained that the objective basis for his opinion was his "years of practice; discussions among peers; conferences; colleagues; review of literature over time; the treatment of my patients and the common, uncomplicated post-operative course." (ECF No. 82-7 at PageID #5532.) He then disputed counsel's characterization of his "personal experience with patients, without a control group, without any form of blinding, is anecdotal evidence." (*Id.* at PageID #5532–33.) Dr. Sinha explained that anecdotal evidence is a type of scientific evidence, but also that he "track[s] my own outcomes on a monthly basis. I track the outcomes for NYU's hospital systems in a case base case log system. We look at a whole series of adverse reactions . . . So when I state that my practice demonstrates a very, very low rare incidence of chronic pain, I know my own data. It is not anecdotal. It's actually founded on data analysis." (*Id.*) In this respect, Dr. Sinha's report is incomplete under Federal Rule of Civil Procedure 26(a)(2)(B)(ii). *See* Fed. R. Civ. P. 26(a)(2)(B)(ii) (stating that an expert "report must contain . . . the facts or data considered by the witness in forming them).

Nevertheless, it is inappropriate to exclude these opinions at this time, as Plaintiffs argue. (ECF No. 82 at PageID #5344.) "If a party fails to provide information or identify a witness as required by Rule 26(a) or (e), the party is not allowed to use that information or witness to supply evidence on a motion, at a hearing, or at a trial, unless the failure was substantially justified or is

harmless." Fed. R. Civ. P. 37(c)(1). In the Sixth Circuit, courts consider five factors to determine whether an omitted disclosure is substantially justified or harmless:

> (1) the surprise to the party against whom the evidence would be offered; (2) the ability of that party to cure the surprise; (3) the extent to which allowing the evidence would disrupt the trial; (4) the importance of the evidence; and (5) the nondisclosing party's explanation for its failure to disclose the evidence.

Howe v. City of Akron, 801 F.3d 718, 748 (6th Cir. 2015) (quoting *Russell v. Absolute Collection Servs., Inc.*, 763 F.3d 385, 396–97 (4th Cir. 2014)).

The balance of factors in this instance counsels permitting Defendants to supply the data, rather exclude Dr. Sinha's opinion. Plaintiffs address only the first prong, asserting that Plaintiffs' counsel was "very surprised." (ECF No. 82 at PageID #5344.) The remaining factors strongly lean toward permitting Defendants to cure the omission. Dr. Sinha testified that he could easily obtain information from the database in about an hour (ECF No. 82-7 at PageID #5553), there is no disruption to the trial because it is more than three months away, the evidence is critical to Dr. Sinha's adverse-event opinions considering how he tacks some of his experience-based opinions to the data, and Defendants represented that they did not believe it was necessary to produce the evidence because Dr. Sinha did not appear to rely on the data in his report (ECF No. 101 at PageID #8588).

Defendants must produce the tracked data for Dr. Sinha's patient-outcome opinions. Plaintiffs will then be permitted to conduct a supplemental deposition of Dr. Sinha related only to this data. The Court declines to address the admissibility of the data-driven opinions under Rule 702 and reserves judgment on any related issues at this time.

Adverse-outcome opinions extending beyond personal experience. Plaintiffs also argue that Dr. Sinha's adverse-event opinions are unreliable because he does not connect some of his opinions to the sources that he relied on as provided in his reliance list or provide citations to that

effect. (ECF No. 82 at PageID #5350.) As an initial matter, this does not render unreliable his otherwise admissible opinions based on his personal experience as a hernia surgeon. However, Dr. Sinha offers other opinions that are not only rooted in his personal experience, such as his opinion that it is not well-established that polypropylene and ePTFE contract at different rates. (*Id.* at PageID #5346.) These opinions are unreliable because they expand beyond Dr. Sinha's personal experience and he has not provided an additional basis for those opinions.

Daubert and Rule 702 require the Court to assess whether Dr. Sinha's opinions are based on sufficient facts or data and whether he has "employ[ed] . . . the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire*, 526 U.S. at 152. Moreover, "[p]roposed testimony must be supported by appropriate validation—*i.e.*, 'good grounds,' based on what is known." *Daubert*, 509 U.S. at 590. For example, if an expert states in his report that he relied on his experience and relevant literature, he must explain how he did so in order for the Court to perform its gatekeeping function. *Hughes v. Kia Motors Corp.*, 766 F.3d 1317, 1329 (11th Cir. 2014).

Dr. Sinha makes sweeping conclusions that necessarily draw on more than his experience, such as an alleged complication not being well-established (ECF No. 82-5 at PageID #5470), and thus he must explain what he has considered and relied on in reaching that conclusion. For instance, the Court takes his opinion that it is not well-established that polypropylene and ePTFE contract at different rates to refer to the medical and/or scientific landscape of research. (*Id.*) The Court cannot discern from his report or his deposition whether Dr. Sinha had good grounds for this conclusion. The reliability of an expert's opinion does not turn on the expert's citing conventions in his expert report, *cf. Speaks v. Mazda Motor Corp.*, 118 F. Supp. 3d 1212, 1220 (D. Mont. 2015), but this does not excuse compliance with *Daubert* and Rule 702. Dr. Sinha's report grapples with

complex medical and scientific issues that he contends are or are not well-established; this necessitates greater assiduity than naked assertions that a complication is or is not supported and providing a reliance list of hundreds of documents as an appendix. (*See* ECF No. 82-5 at PageID #5505–09.) District courts are not tasked with grading or checking the substance of an expert's opinions as gatekeepers under *Daubert*, but *Daubert* requires that courts ensure experts employ the requisite level of rigor in forming their opinions, which means that experts must show their work.

Defendants counter that Dr. Sinha explained the basis of his opinions in his deposition testimony by "point[ing counsel] to precise literature" (ECF No. 101 at PageID #8595), but Dr. Sinha's references to literature are not precise. Although he cites to data from various hernia societies, Dr. Sinha refers vaguely to articles and studies throughout the deposition. (*E.g.*, ECF No. 101-2 at PageID #8652–53.) True, Plaintiffs' counsel could have asked more questions during this deposition and Dr. Sinha can be cross-examined at trial on the bases for his opinions, as Defendants argue. (ECF No. 101 at PageID #8595.) But this is only proper if the Court can find as a preliminary matter that Dr. Sinha's opinions are reliable, and the Court does not find so here.

B. Polypropylene degradation and biomaterial testing

Next, Plaintiffs assert that Dr. Sinha is unqualified to opine on the validity of biomaterial testing and that his opinions on polypropylene mesh degradation are unreliable. (ECF No. 82 at PageID #5351.) The Court agrees that Dr. Sinha is unqualified to opine on the capacity of biomaterials testing and that some of his polypropylene mesh degradation opinions are unreliable. Dr. Sinha's experience-based polypropylene degradation opinions are reliable, though.

Dr. Sinha is not qualified to opine on the validity of biomaterial testing. In this MDL, the Court has permitted experts who are hernia surgeons to offer degradation opinions from the

perspective of a surgeon, which includes "mesh degradation on a large scale, focusing on the ways a polypropylene mesh product can change after implantation in the body." *In re Davol, Inc./C.R. Bard, Inc.*, 2020 WL 6605612, at *9 (quoting *Wilkerson v. Bos. Sci. Corp.*, No. 2:13-CV-04505, 2015 WL 2087048, at *20 (S.D.W. Va. May 5, 2015)) (EMO No. 7). But Dr. Sinha's opinion here extends beyond mesh degradation on a large scale and beyond the perspective of a hernia surgeon. Dr. Sinha opines that microscopic and spectroscopic testing of polypropylene does not demonstrate polypropylene degradation. (*E.g.*, ECF No. 82-7 at PageID #5561–64.) Defendants do not demonstrate that Dr. Sinha has materials or other scientific experience that qualifies him to offer this opinion. Defendants refer to Dr. Sinha's deposition testimony in which he references his master's degree in electrical engineering, his familiarity with solid state chemistry, and expertise in material science via electro-optics at MIT. (ECF No. 101 at PageID #8598 n.20.) But without more explanation, the Court cannot assess how these experiences qualify Dr. Sinha to opine about the limits of micro- and spectroscopic testing in this context. Accordingly, Defendants do not meet their burden to demonstrate how this qualifies Dr. Sinha to offer these opinions.

Dr. Sinha's opinions regarding polypropylene degradation are reliable to the extent that they are based on his experience, but his remaining opinions are unreliable. Plaintiffs identify opinions such as that Dr. Sinha has never seen polypropylene mesh behave in certain ways that would indicate degradation. (ECF No. 82 at PageID #5345–46.) As set forth above, his opinions are reliable to the extent that the relies on his own surgical experience and observations in his patients. *Supra* Part III.A. Plaintiffs counter that Dr. Sinha's opinions are "subjective" and "conclusory," and so the Court cannot their reliability. (*Id.* at PageID #5341.) Dr. Sinha's personal experiences and observations with regard to degradation, or the lack thereof, in his patients conveys sufficient reliability. For example, Dr. Sinha testified that he had not seen fissures in the

polypropylene meshes *in vivo* and that he has not seen anything in his patients that would suggest polypropylene does not "function decades after his has been implanted." (ECF No. 82-7 at PageID #5550, 5593.) This is a sufficient explanation of his personal experiences with patients. At bottom, "[v]igorous-cross examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible" expert testimony. *Daubert*, 508 U.S. at 596.

But as with Dr. Sinha's adverse event opinions, his opinions that necessarily extend beyond his experience are unreliable because he does not identify a basis for his opinions. Plaintiffs challenge Dr. Sinha's opinions that he has never seen evidence or clinical outcomes support that polypropylene degrades and that he disagrees that polypropylene degrades. (ECF No. 82 at PageID #5345–46, 5351.) They also challenge Dr. Sinha's opinions from his deposition that degradation and changes in polypropylene detected by microscopic testing have no clinical relevance and that it is not well-accepted that polypropylene degrades. (*Id.* PageID #5351–52.) As before, it is impossible to assess what medical research or other evidence Dr. Sinha relied upon and rejected in reaching his expansive conclusions because he does not specific so in his report or deposition. Therefore, his opinions are unreliable and inadmissible. *Supra* Part III.A.

C. Specific causation and case specific opinions

Plaintiffs argue that Dr. Sinha has not offered specific causation or case specific opinions, and so he should not be permitted to offer any such opinions. (ECF No. 82 at PageID #5356.) Defendants are clear that Dr. Sinha will offer no such opinions (ECF No. 101 at PageID #8576–77 & n.3, 8580–81), which Plaintiffs acknowledged in their reply brief, (ECF No. 133 at PageID

#11432). Accordingly, this part of Plaintiff's motion is denied as moot.[4]

D. Ventralex IFU and 510(k) process

Plaintiffs contend that Dr. Sinha should not be permitted to opine that the Ventralex IFU was an adequate warning and that 510(k) clearance from the FDA is a determination that the device is safe and effective. (ECF No. 82 at PageID #5356–58.) Dr. Sinha may opine that from his perspective as a hernia surgeon, the Ventralex IFU sufficiently apprised him of the pertinent risks, but he may not offer opinions the legal or regulatory adequacy of the IFU or the meaning of 510(k) clearance.

First, Dr. Sinha's Ventralex IFU opinions. As this Court explained in *Johns v. C.R. Bard, et al.*, the first bellwether in this MDL, no expert may offer opinions about the legal or regulatory adequacy of warnings, but experts may offer opinions about whether the warnings sufficiently apprised hernia surgeons of the risks of the Ventralight ST from the vantage point of the end-user. *E.g.*, *In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Prods. Liab. Litig.*, --- F. Supp. 3d ----, Nos. 2:18-md-2846, 2:18-cv-1509, 2021 WL 2643110, at *5 (S.D. Ohio June 28, 2021) (EMO No. 13). Accordingly, Dr. Sinha may offer opinions from his vantage point as an end user, a hernia surgeon who has used the Ventralex and similar devices. *See id.* (noting that an expert "must have some on-point experience, such as conducting hernia surgeries with mesh devices"). Indeed, Plaintiffs do not dispute his qualifications as a hernia surgeon. (*See* ECF No. 82 at PageID #5356–57.) For example, he stated in his report that the IFU was adequate considering that the complications at issue are well-known in the medical community and considering surgical training.

[4] Defendants argue that general causation expert testimony may be admissible even if the expert does not also provide specific causation testimony. (ECF No. 8580–83.) The Court agrees, but Plaintiffs do not raise that argument. (ECF No. 133 at PageID #11430.)

(ECF No. 82-5 at PageID #5462.) However, Defendants contend that Dr. Sinha will also opine on the adequacy of the IFU "from the perspective of a former medical device manufacturer employee who actively worked on FDA submissions" who is familiar with the regulatory requirements. (ECF No. 101 at PageID #8587.) Qualifications aside, Dr. Sinha cannot offer this opinion because it is an impermissible regulatory and legal adequacy opinion.

Next, Dr. Sinha's 510(k) opinions. This Court had repeatedly held that "[t]he Court shall instruct the jury on the § 510(k) process and explain that the § 510(k) process does not mean that the FDA vouches for the safety of the device or that the FDA conducts any independent testing on the device. No experts will be permitted to opine on the background or legal meaning of the process." *In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Prods. Liab. Litig.*, Nos. 2:18-md-2846, 2:18-cv-1509, 2020 WL 6603657, at *8 (S.D. Ohio Oct. 20, 2020) (Motions in Limine Order ("MIL") No. 4). Dr. Sinha opines in his report that "[t]he FDA is the regulatory agency in the United States charged with overseeing the clearance of Class II medical devices like hernia mesh, finding them to be 'substantially equivalent' to a predicate under the 510(k) process *and, in turn, safe and effective for use by surgeons across the country*." (ECF No. 82-5 at PageID #5473–74 (emphasis added).) This is an opinion about the background and legal meaning of the 510(k) process, and he may not offer it.

Defendants counter that Dr. Sinha is qualified to offer this opinion given his previous experience working for a medical device manufacturer (ECF No. 101 at PageID #8586–57), but again, even the most qualified witness cannot give a legal opinion. Defendants argue that Dr. Sinha will not usurp the Court's role or offer any legal opinions" and "[i]nstead . . . will respond to arguments raised by Plaintiffs." (*Id.* at PageID #8586.) But the nature of Dr. Sinha's opinion is about the meaning for 510(k) clearance, which is impermissible.

E. Legal and ethical opinions

Plaintiffs then challenge Dr. Sinha's opinions that they characterize as legal or ethical conclusions. (ECF No. 82 at PageID #5358–60.) For example, Defendants identify Dr. Sinha's opinion that "no product defect, action, or inaction on the part of Bard or Davol causes hernia repair complications." (ECF No. 82-5 at PageID #5476.) Dr. Sinha cannot offer such opinions.

Dr. Sinha cannot opine that there was no design defect or action of Defendants that caused Mr. Milanesi's injuries because they are legal conclusions. In *Johns*, the Court concluded that a materially identical statement in Dr. Maureen Reitman's report was inadmissible on this basis. (Case No. 2:18-cv-1509, ECF No. 425 at PageID #22493–94 (EMO No. 8).) The Court also explained that Dr. Reitman, a materials scientist, "can speak to the specific issue of whether the design or manufacture of the Ventralight ST caused Plaintiff's injuries by oxidatively degrading, which may suggest the answer to the ultimate question of causation—did Defendants cause Plaintiff's injuries." (*Id.* at PageID #22494.) The same reasoning applies here. Dr. Sinha can opine from the perspective of an expert hernia surgeon that the defects Plaintiffs claim occurred could not have caused Mr. Milanesi's injuries, but he cannot offer conclusions that constitute legal opinions, such as that no act of Defendants caused Mr. Milanesi's injuries. Moreover, such a broad statement necessarily extends beyond Dr. Sinha's expertise because other non-medical issues present in this case, including molecular-level and material selection issues. (*See id.* at PageID #22493–94.) Defendants counter that statements such as these from Dr. Sinha's report "merely encapsulates Dr. Sinha's general opinion" from his medical perspective.[5] (ECF No. 101 at PageID #8599.) But as described above, his opinions exceed these bounds.

[5] Plaintiffs argue that Dr. Sinha also offers corporate state of mind opinions to the extent that he opines Defendants conduct as reasonable. (ECF No. 82 at PageID #5359–60.) The Court's reading of Dr. Sinha's report reveals no such opinion.

F. Gold standard and standard of care

Plaintiffs contend that Dr. Sinha should not be permitted to offer opinions that polypropylene mesh is the gold standard for hernia repairs or to reference the "standard of care." (ECF No. 82 at PageID #5360.) Defendants acknowledge the Court's previous ruling excluding references to polypropylene as the "gold standard" and represent that Dr. Sinha will not use these terms as he did in his report but will instead use the term "medical standard of care." (ECF No. 101 at PageID #8599.) This is consistent with the Court's decision in *Johns* that Defendants "may not introduce evidence of the 'gold standard' . . . but Bard may use the term "medical standard of care," and not to refer to the 'standard of care,' as that is a different, [legal] determination." *In re Davol, Inc./C.R. Bard, Inc.*, *Polypropylene Hernia Mesh Prods. Liab. Litig.*, Nos. 2:18-v-01509, 2:18-md-2846, 2020 WL 6605648, at *2 (S.D. Ohio Sept. 11, 2020) (MIL No. 3).

IV. Conclusion

For these reasons, Plaintiffs' motion to exclude Dr. Sinha's opinions and testimony (ECF No. 82) is **GRANTED IN PART, DENIED IN PART, AND DENIED IN PART AS MOOT**. Defendants must produce the data that Dr. Sinha relied upon on his deposition, and Plaintiffs may conduct a supplemental deposition of Dr. Sinha only regarding his adverse-outcome opinions that relied on the previously undisclosed data.

IT IS SO ORDERED.

10/22/2021
DATE

s/ Edmund A Sargus, Jr.
EDMUND A. SARGUS, JR.
UNITED STATES DISTRICT JUDGE